CIRCULAR LETTER: DHCQ 03-10-436

TO: Hospice Administrators

FROM: Paul I. Dreyer, Ph.D., Director

RE: Amendments to Hospice Program Licensure Regulations (105 CMR 141.000) and Clinical Laboratory Improvement Amendments (CLIA) Requirements for Laboratory Tests

DATE: October 24, 2003

The purpose of this memorandum is to clarify the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as they apply to hospice programs licensed in Massachusetts. Under the CLIA requirements, all laboratory testing must be performed by laboratories that are federally certified and licensed by the Commonwealth.

CLIA requires all entities that perform even one test, including a waived test, on "...materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings" to meet certain federal requirements. If an entity performs tests for these purposes, it is considered under CLIA to be a laboratory and must register with the CLIA program.

Hospice services, which include hospice inpatient facilities under recently promulgated amendments to the Massachusetts hospice program licensure regulations at 105 CMR 141.000, may apply for a CLIA certificate of waiver to perform either of the following tests: blood glucose (waived technology only) or fecal occult blood. No other tests on the list of waived tests may be performed by a hospice program under a certificate of waiver, including previously issued certificates of waiver. A licensed and certified laboratory must perform all other laboratory tests.

A hospice program must apply for and receive, through the Department's Clinical Laboratory Program, a Centers for Medicare and Medicaid Services (CMS) certificate of waiver prior to performing either of these tests on its patients either at home or in a hospice inpatient facility directly owned and operated by the hospice program. A hospice program's certificate of waiver covers the tests conducted in the hospice patients' homes and in its hospice inpatient facility, where applicable.

For further information about the CLIA requirements for a certificate of waiver, please refer to the following federal CLIA website: http://www.phppo.cdc.gov or contact Doris Moore, Director of the Department's Clinical Laboratory Program, at (617) 983-6732.

cc Doris Moore, Director, DPH Clinical Laboratory Program